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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

REC'D 14 JUN 2005

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Applicant's or agent's file reference 12224PC1	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU2003/000796	International Filing Date (day/month/year) 25 June 2003	Priority Date (day/month/year) 25 June 2003
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ B29C 70/46, 70/20, 70/22, B32B 5/12, A61F 2/60		
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1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 10 sheet(s).

3. This report contains indications relating to the following items:

- | | | |
|------|-------------------------------------|---|
| I | <input checked="" type="checkbox"/> | Basis of the report |
| II | <input type="checkbox"/> | Priority |
| III | <input type="checkbox"/> | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| IV | <input type="checkbox"/> | Lack of unity of invention |
| V | <input checked="" type="checkbox"/> | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| VI | <input type="checkbox"/> | Certain documents cited |
| VII | <input type="checkbox"/> | Certain defects in the international application |
| VIII | <input type="checkbox"/> | Certain observations on the international application |

Date of submission of the demand 20 January 2005	Date of completion of the report 1 June 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer M. BREMERS Telephone No. (02) 6283 2052

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description, pages 1-7, 13-35 as originally filed,
pages , filed with the demand,
pages 8-12 received on 25 May 2005 with the letter of the same
- ☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 36-40 received on 25 May 2005 with the letter of the same
- ☒ the drawings, pages 1-10 as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-26	YES
	Claims	NO
Inventive step (IS)	Claims 1-26	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-26	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

None of the documents cited in the International Search Report disclose the combination of a prosthesis of varying weights made in a single cavity mould and having a folding step as defined in (b) of claim 1. Therefore, the claims are novel and inventive.

dimensions when additional plies or laminae were used to increase thicknesses or widths of prostheses. In other words it was necessary to use different mould cavity dimensions to correspond to different weights or different weight categories of prosthesis. The necessity of different thicknesses or widths was necessary to provide a variety of prostheses with different dimensions, thereby providing a disparity of thicknesses or widths to accommodate variations of pliability rates to support different exoskeleton and endoskeleton frames, body types and activity requirements of amputees.

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OBJECT OF THE INVENTION

It has now been found that the above deficiencies of conventional manufacturing processes of conventional prostheses may now be reduced or overcome by the advent of the present invention where variations in requirements of individual users inclusive of amputees can be obtained by a process, as described hereinafter, which has the capability to make prosthesis inclusive of prostheses having a range of different weights or different weight categories in a single dimensional cavity mould, thus, making the process not only more efficient, but also less expensive.

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SUMMARY OF THE INVENTION

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In one aspect of the invention, there is provided a method of construction of a prosthesis for patients of various weight categories, , said method including the steps of:

(a) impregnating non-metallic fibres in a thermosetting resin whereby said impregnated fibres are arranged to form a sheet of said

fibres;

(b) folding the sheet by bending adjoining parts of the sheet along adjacent fold lines therebetween so that said fibres are arranged in an intersecting orientation to form a prepreg having a double layer of fibres in different planes with the fibres in each layer having a different angle of orientation to a longitudinal axis of the prepreg;

(c) cutting a plurality of pre-pegs from said sheet formed in step (b);

(d) forming layers of said pre-pegs obtained from step (c) so that said layers are arranged in stacked relationship in a mould cavity of a compression mould whereby the mould cavity has a constant volume for each of the various weight categories;

(e) compression moulding at elevated temperature; and

(f) removing the prosthesis from the compression mould.

In step (a) although the sheet can be produced by either solution drum winding or a hot melt technique as hereinafter described, it is preferable to use the drum winding technique so as to provide an intermediate composite sheet formed of the fibres supported on a sheet of release paper, whereby upon removal of the release paper, the final sheet formed by step (a) is obtained after cutting the intermediate sheet as it is supported on the drum. Preferably all of the fibres in the sheet are oriented in the same or similar direction and thus may be described as unidirectional (UD).

In an alternative hot melt technique which may be used instead of

the solution drum winding as described above in step (a) the pre-peg formed using said technique has fibers that are continuous and that are laid onto a continuous sheet of release paper after the hot melt resin impregnation. These hot melt unidirectional pre-pegs can be stored in rolls
5 of e.g. 75m, 100m, 150m or 200m per roll.

A significant difference between drum wound UD pre-peg and hot melt UD pre-peg is in the longitudinal length of these pre-pegs. The longitudinal length of drum wound UD pre-peg is determined by the circumference of the drum (eg. a drum with 1.90m circumference can only
10 produce a UD pre-peg of 1.90m) whereas hot melt UD is continuous longitudinally and available in rolls of 75m, 100m, 150mm or 200mm per roll as referred to above.

The intermediate sheet may be cut at a variety of different angles so as to provide the pre-pegs of intersecting fibres and such angles may
15 be 15°, 22½°, 30°, 45° or 60° or any other suitable angle so that the final sheet has sloping sides having the desired angle to vertical. Then the final sheet may be folded back upon itself so as to form a pre-peg or laminate sheet having intersecting fibres from which the pre-pegs may be cut out as hereinafter described.

20 These pre-pegs may be alternated with pre-pegs that have each of the fibres arranged longitudinally or latitudinally to each other and which may be formed by the drum winding technique as discussed above so as to provide a final sheet which may be in the shape of a rectangle or square. Thus, pre-pegs having the longitudinally or latitudinally oriented

fibres may then be cut out from the final sheet.

The cutting of the intermediate sheet as described above may be carried out by cutting lines or grooves which are formed on an outer surface of the drum and arranged at the desired angle, e.g. 0° for forming pre-pegs of longitudinally or latitudinally arranged fibres and 60° or 45° for forming pre-pegs of intersecting fibres.

Another significant difference between the solution drum winding as discussed above and the hot melt technique as discussed above is that instead of the cutting lines or grooves being formed on the drum in the solution drum winding technique in contrast in the hot melt technique the desired angles (say 15°, 22^{1/2}°, 30°, 45° or 60 degrees) will have to be cut physically on the pre-peg sheets.

The method of construction of the invention allows the fabrication of a lightweight, inexpensive prosthesis made of composite material for amputees and, more particularly, to an improved lower limb prosthesis. Such a moulding method is effective for overcoming the limitations in the strength, dynamic endurance, weight problems of fibreglass and the stiffness/rigidity and fatigue limitations of prior art methods described above.

The method of construction of the invention using non-metallic fibres in combination with an epoxy resin ensures that all individual fibres are impregnated to allow better dynamic endurance and a reduction in weight and thickness whilst retaining the natural flexibility and response of its fibres to allow the prosthesis to have a smoother transition from heel

prosthesis to have a smoother transition from heel strike through to toe-off. Another advantage is that it allows better shock dispersion of the resilient constructed matrix that dissipates loads during heel strike.

While the device of the present invention is preferably constructed
5 of epoxy resin reinforced with laminates of carbon and/or glass fibres, it may be constructed of other non-metallic fibres such as aramid fibre, or recently developed synthetic fibres.

Preferably the prosthesis is a pylon which suitably is J shaped.

Preferably, said pylon, at least in outer extremities thereof having
10 regard to a lateral dimension or thickness of the pylon, is formed from a laminate of alternating layer(s) of said intersecting fibres with some layer(s) of said fibres arranged in longitudinal and latitudinal orientation.

The prosthesis may also comprise the J-shaped pylon in combination with a sole plate wherein the sole plate incorporates an
15 anterior toe section and posterior heel section. The sole plate may also be formed from the same composite material as the J-shaped pylon. The prosthesis may also comprise the sole plate per se.

The J-shaped pylon may have an upper shin mounting portion, a lower shin portion and an ankle zone. The ankle zone may
20 taper in thickness from an upper part adjacent to the lower shin portion towards a lower end of the ankle zone.

The upper shin mounting portion, preferably has a substantially constant thickness and width. The lower shin portion may have a width or lateral dimension that diverges outwardly as it approaches
25 the ankle zone. The ankle zone, at or approaching a lower or free end thereof, may have a slight concave curvature.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A method of construction of a prosthesis for patients of various weight categories, said method including the steps of:

- 5 (a) impregnating non-metallic fibres in a thermosetting resin whereby said impregnated fibres are arranged to form a sheet of said fibres;
- (b) folding the sheet by bending adjoining parts of the sheet along adjacent fold lines therebetween so that said fibres are arranged in an intersecting orientation to form a prepeg having a double layer of fibres in different planes with the fibres in each layer having a different angle of
- 10 orientation to a longitudinal axis of the prepeg;
- (c) cutting a plurality of pre-pregs from said sheet formed in step (b);
- (d) forming layers of said pre-pregs obtained from step (c) so that said layers are arranged in stacked relationship in a mould cavity of a
- 15 compression mould whereby the mould cavity has a constant volume for each of the various weight categories;
- (e) compression moulding at elevated temperature; and
- (f) removing the prosthesis from the compression mould.

- 20 2. A method as claimed in claim 1 wherein in step (a) use is made of a drum winding technique whereby said impregnated fibres are wound onto a drum so as to provide an intermediate composite sheet formed of the fibres supported on a sheet of release paper on the drum, whereby upon removal of the release paper, the sheet formed by step (a) is obtained

by cutting the intermediate sheet as it is supported on the drum.

3. A method as claimed in claim 1 wherein use is made of a hot melt technique wherein after hot melt resin impregnation of the fibres they are laid onto a continuous sheet of release paper and subsequently
5 stored as rolls.

4. A method as claimed in claim 1 wherein in step (d) layers of said pre-pegs having fibres arranged in an intersecting orientation are mixed with layers of pre-pegs which have all of their fibres arranged in a latitudinal and/or longitudinal orientation.

10 5. A method as claimed in claim 1 wherein in step (d) layers of said pre-pegs having fibres arranged in an intersecting orientation are alternated with layers of pre-pegs having all of their fibres arranged in a latitudinal and/or longitudinal direction.

6. A method as claimed in claim 1 wherein in step (d) there
15 is a lay up sequence in the mould cavity wherein layers of pre-pegs having fibres arranged in an intersecting orientation are followed by layers of pre-pegs having their fibres arranged in a longitudinal and/or latitudinal orientation followed by layers of pre-pegs having their fibres arranged in an intersecting orientation.

20 7. A method as claimed in claim 1 wherein in step (d) successive layers are formed of pre-pregs having fibres arranged in an intersecting orientation which alternate with pre-pregs having fibres arranged in a longitudinal and/or latitudinal orientation.

8. A method as claimed in claim 1 wherein in step (c) the

intermediate sheet is cut at a variety of different angles selected from the group consisting of 15° , $22^{1/2^\circ}$, 30° , 45° and 60° so that the final sheet has sloping sides having an acute angle to vertical before folding of the final sheet upon itself to form said pre-peg.

5 9. A method as claimed in claim 8 wherein the angle is selected from 30° and 45° .

10 10. A method as claimed in claim 2 wherein the cutting of the intermediate sheet is carried out by provision of cutting lines or grooves which are formed in an outer surface of the drum at an angle selected from the group consisting of 15° , $22^{1/2^\circ}$, 30° , 45° and 60° for pre-pegs of intersecting fibres.

15 11. A method as claimed in claim 4 wherein said pre-pegs having fibres arranged in a latitudinal and/or longitudinal orientation are formed from an intermediate sheet which intermediate sheet is cut at an angle of 0° for longitudinal fibres and 90° for latitudinal fibres having regard to a longitudinal axis of a drum supporting the intermediate sheet.

12. A method as claimed in claim 1 wherein step (d) is carried out in a mould cavity having the same dimensions for different weights or different weight categories of moulded product.

20 13. A prosthesis for patients of various weight categories formed from composite materials having layers of non-metallic fibres impregnated with a thermosetting resin, characterized in that said prosthesis is formed at least partly from double layers of non continuous or cut fibres in different planes wherein the fibres are arranged in an intersecting orientation

wherein the fibres in each layer have an accurately predetermined different angle of orientation to a longitudinal axis of the prosthesis whereby said prosthesis has varying areas of fibre area weight along its length to provide said prosthesis with differential locations of stiffness and flexibility to enhance whereby thereof and said prosthesis has the same dimensions or number of layers of fibres regardless of the weight category of the patient.

14. A prosthesis as claimed in claim 13 in the form of a pylon.

15. A prosthesis as claimed in claim 13 in the form of a J shaped pylon.

16. A prosthesis as claimed in claim 13 in the form of a sole plate.

17. A prosthesis as claimed in claim 13 in the form of a combination of a J shaped pylon attached to a sole plate so as to define a lower limb prosthetic device.

18. A prosthesis as claimed in claim 13 wherein the pylon at least in outer extremities thereof is formed from a laminate of alternating layers of said intersecting fibres with layer(s) of said fibres arranged in longitudinal and/or latitudinal orientation.

19. A prosthesis as claimed in claim 15 wherein the J shaped pylon has an upper shin mounting portion, a lower shin portion and an ankle zone.

20. A prosthesis as claimed in claim 19 wherein the upper shin mounting portion has a substantially constant thickness and width.

21. A prosthesis as claimed in claim 19 wherein the lower shin portion has a width that diverges outwardly as it approaches the ankle zone.

5 22. A prosthesis as claimed in claim 19 wherein the ankle zone at or approaching a lower or free end thereof has a slight concave curvature.

23. A prosthesis as claimed in claim 17 wherein the sole plate is of substantial width compared to an ankle zone of the J shaped pylon.

10 24. A prosthesis as claimed in claim 16 wherein the sole plate has a heel portion and a toe portion.

25. A prosthesis as claimed in claim 23 wherein the sole plate has a heel portion, a toe portion and a heel portion wherein the heel portion has a complementary or corresponding curvature to the ankle zone
15 where they abut each other.

26. A prosthesis as claimed in claim 13 which has substantially the same dimensions and shape regardless of weight.